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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Armin Bernhard

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EXAMINER

FLORY, CHRISTOPHER A

ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

05/08/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/508,806	Applicant(s) BERNHARD, ARMIN	
	Examiner CHRISTOPHER A. FLORY	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2009 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 10 March 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Excitation device 50, which Applicant is attempting to amend into the first full paragraph of page 6. There is no previous disclosure of such an excitation device in any of the Specification, drawings or claims prior to the 10 March 2009 amendment. This is evident because the excitation device 50 was not previously shown or suggested in the drawings, and does not relate to the other discussion in the amended paragraph or the rest of the Specification.

Signal processor 60, which Applicant is attempting to amend into the first full paragraph of page 7. There is no previous disclosure of a signal processor in any of the Specification, drawings or claims prior to the most recent amendment. This is evident because the signal processor 60 was not previously shown or suggested in the drawings, and does not relate to the other discussion in the amended paragraph or the rest of the Specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Drawings

2. The drawings are objected to because excitation device 50 in Figure 1 and signal processor 60 in Figure 5 are considered to be new matter that was not present in the original disclosure of the Application. This is further evidenced by Applicant's attempt to add the same new matter into the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings submitted 10 March 2009 are considered to contain new matter as described above. The corrected drawings are required in reply to the

Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Response to Arguments

4. Applicant's arguments filed 10 March 2009 have been fully considered but they are not persuasive.
5. Regarding Puria, Applicant argues that the reference does not teach conversion of force into electric signal. However, such a conversion is an inherent property of a piezo-type device such as the one disclosed in Puria. Applicant also argues that the ossicular chain is not permanently interrupted. However, Applicant is drawn to e.g. Figures 4C and 4D which show the device between the bones of the chain which can thus clearly be considered interrupted.
6. Regarding Ball, Applicant again argues that the reference does not teach conversion of force into electric signal. Again, such a conversion is an inherent property of a piezo-type.
7. Applicant's remaining arguments are considered moot in light of the above reasoning, and in light of the rejections as presented herein below.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
10. Regarding claim 1, there is no support for a signal processing unit.
11. Regarding claim 16, there is no support for a signal processing unit or an excitation means.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1 and 13-16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bisch et al. (US 5,282,858, hereinafter Bisch'858).

Bisch'858 discloses a sound receiver for a fully implantable hearing aid (title; abstract) comprising an implantable electromechanic transducer (abstract); at least one of an impedance or A/D converter (column 6, lines 16-27) and wherein conversion of an

impedance signal is an inherent function of a microphone or sound transducer; a signal processing unit (abstract); feedlines (e.g. 36, 38 in Fig. 1) a mounting mechanism (e.g. as seen in Fig. 4); and wherein the transducer is rigidly fixed to malleus or incus, with the ossicular chain permanently interrupted and the incus moveable independent of the stapes (Figs. 2 and 4; column 3, lines 21-37; column 4, lines 31-50; column 5, line 39 through column 6, line 15).

Claim Rejections - 35 USC § 102/103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 1 and 13-16 are rejected under 35 U.S.C. 102(e) as clearly anticipated by Puria et al. (US 6,629,922, hereinafter Puria'922) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Puria'922 in view of Baumann et al. (US Patent Publication 2002/0138115).

Particular emphasis is placed on Figures 1A, 2E, 2F, 4C, 4D and their related paragraphs. Regarding the limitation of an impedance or A/D converter, the conversion of an impedance signal is an inherent function of a piezoelectric device such as the one disclosed in Puria'922. Puria'922 discloses a signal processing unit in column 9, lines 40-41. Puria'922 discloses that the electromechanic transducer unit is rigidly fixed to

malleus or incus with the ossicular chain permanently interrupted and the incus moveable independent of the stapes (Abstract; column 5, lines 45-62).

Alternatively, in the same field of endeavor, Baumann et al. teaches an implantable hearing aid with both an A/D converter (Fig. 2, A/D converters 30 and 31; paragraphs [37]-[40]) and an impedance transformer (paragraph [66]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Puria'922 with the A/D converter and impedance transformer of Baumann et al. to provide the same advantages of more efficiently processing data and amplifying the input voltage.

16. Claims 1 and 13-16 stand rejected under 35 U.S.C. 102(b) as anticipated by Ball et al. (US Patent 5,624,376, hereinafter referred to as Ball'376) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ball'376 in view of Kroll et al. (US 6,540,662, hereinafter Kroll'662) or in view of Brillhart et al. (US 6,585,637, hereinafter Brillhart'637) or alternatively further in view of Baumann et al. (US Patent Publication 2002/0138115).

Ball'376 discloses a sound receiver for a fully implantable hearing aid (TITLE; ABSTRACT) comprising an implantable electromechanic transducer which converts the force resulting of an accelerated mass into an electric signal (Figs. 3-5, transducer 100; ABSTRACT); a signal processing unit (column 7, lines 48-55; column 11, line 9; Fig. 22 processor 804); the sound receiver providing a mounting mechanism on at least one of the ossicles in the ossicle chain (abstract; Figs. 8-10; Fig. 5, titanium prongs 52).

Impedance conversion is inherently performed in a piezo transducer as disclosed in Ball'376, and the piezo sensor is therefore considered to read on the limitation of an

impedance converter (ABSTRACT; column 3, lines 24-45). Alternatively, in the same field of endeavor, Baumann et al. teaches an implantable hearing aid with both an A/D converter (Fig. 2, A/D converters 30 and 31; paragraphs [37]-[40]) and an impedance transformer (paragraph [66]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Ball'376 with the A/D converter and impedance transformer of Baumann et al. to provide the same advantages of more efficiently processing data and amplifying the input voltage.

Specifically regarding the clause that the sound receiver be rigidly fixed to the malleus or incus, whereby incus and stapes, or any replacement thereof, are disconnected so that the incus can move independently from the stapes or any replacement thereof, the embodiments of Ball'376 shown in Figure 9 can be reasonably interpreted as anticipating this claim limitation. Regarding Figure 9, a partial prosthetic embodiment, Ball'376 shows the sound transducer 100 connected to the incus MM by way of a prosthetic member 38c. Since member 38c and sound transducer 100 form a singular prosthetic device, sound transducer 100 can reasonably be interpreted as being rigidly connected to the incus since subcomponent 38a is rigidly fixed to both the transducer and the incus. Although it is not a direct connection, it is nonetheless a rigid connection. In this embodiment, the stapes is completely removed from the system. It is very clear that in this case, the incus and stapes are permanently disconnected from one another and are now moving independently. Contrary to Applicant's arguments, removal of the stapes does not in any way suggest that Ball'376 "fails to teach a stapes at all," since the stapes must be taught in order to teach that the stapes is removed.

Additionally, removal of the stapes does not prevent Ball'376 to read on the currently amended claims, which simply state that "the incus and stapes are permanently disconnected," which in no way provides necessity of the stapes to remain within the body.

Alternatively, in the same field of endeavor, Kroll'662 teaches that a removal of the stapes (i.e. a permanent disconnect of the incus from the stapes) acts to disarticulate the ossicular chain to prevent feedback and permit the malleus and incus to remain in place, which further aids in preventing damage from acoustical trauma by allowing the natural musculoskeletal defense mechanisms to protect against it (column 5, lines 40-50; column 6, line 51 through column 7, line 7). Similarly, in the same field of endeavor, Brillhart'637 teaches that disarticulation of the ossicular chain creates a feedback barrier to prevent retrograde transmission of sound energy through the external auditory canal and tympanic membrane to the microphone, and further defines an embodiment (Fig. 4) in which the incus and stapes are disarticulated and fixed within the middle ear but not removed with a separation of 2-3 millimeters in order to prevent a rejoining of the two bones (column 5, lines 37-43; column 6, line 62 through column 7, line 21). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system and method of Ball'376 with a permanent disconnection of the incus and stapes as taught by either Kroll'662 or Brillhart'637 to provide the Ball'376 system and method with the same advantages of preventing retrograde feedback of sound energy to the microphone and prevent acoustical trauma

by allowing the natural musculoskeletal defense mechanisms to protect against such trauma.

It is further noted that each of the applied references is considered to positively read on the newly amended limitation of feedlines connecting the sound receiver to a signal processing unit. Namely Ball'376 shows leads 24 in Figures 4, 10, 14, 18, 19a, 23 and 24, each of which is considered to be a feedline. Kroll'662 shows feedlines in Figure 3, element 110; Figure 5, element 160; and Figure 6, element 126. Brillhart'637 shows feedlines clearly in Figures 3 and 7.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christopher A. Flory/
6 May 2009

/George Manuel/
Primary Examiner